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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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04/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,677	DAO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-13,15,17-21 and 23-47* is/are pending in the application.

4a) Of the above claim(s) *2-4,12,13,15,20,21,24,25,27-30,33-38,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,10,11,17-19,23,26,31,32,39-43,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/09/2010.

Claims 1-5, 10-13, 15, 17-21, 23-46 previously presented, claim 47 is currently added. Claims 1-5, 10-13, 15, 17-21, 23-47 are pending.

Claims 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30, 33-38 are drawn to nonelected invention. Election was made with traverse in the reply filed on 12/03/2007. Claims 44 and 45 were withdrawn from consideration in the office action mailed 04/09/2009 as being directed to non-elected invention by original presentation.

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 and 47 are included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 18 are confusing because claim 17

recites that the therapeutic agent and microparticles are admixed together, while claim 1 requires the therapeutic agent and the microparticles are present as separate entities and the therapeutic agent is present between the microparticles, and not mixed with the microparticles. Claim 18 recites microparticles are applied to the adhesive followed by application of the therapeutic agent, and this will create two layers and not the therapeutic agent and the microparticles present as separate entities and the therapeutic agent is present between the microparticles as recited by claim 1.

Response to Arguments

3. Applicant's arguments filed 02/09/2010 have been fully considered but they are not persuasive. Applicants' argue that the rejection was based on confusion arising from the Examiner's understanding that the claimed pockets referred to pockets within the microparticles, whereas the claimed pockets instead intended to refer to pockets (i.e., spaces) between the microparticles. Such pockets may be formed, for example, by the processes described in claims 17 and 18, among others. This confusion is believed to have been rectified by the above amendment to claim 1.

In response to this argument, it is argued that claims 17 and 18 as still confusing even with the amendment made to claim 1 because claim 17 recites that the therapeutic agent and microparticles are admixed together, while claim 1 requires the therapeutic agent and the microparticles are applied as separate entities and the therapeutic agent is present between the microparticles, and not mixed with the microparticles. Claim 18 is confusing because the claim recites that microparticles are applied to the adhesive

followed by application of the therapeutic agent, and this will create two layers and not the therapeutic agent and the microparticles are applied as separate entities and the therapeutic agent is present between the microparticles as recited by claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (WO 02/26162, currently listed on PTO 892, and copy is provided) combined with Pilliar (US 3,855,638, currently listed on PTO 892)

Applicant Claims

Currently amended claim 1 is directed to medical article comprising:

(a) an adhesive region comprising an adhesive;

(b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and

(c) microparticles, at least a portion of which are attached to said surface of said adhesive region, wherein said therapeutic agent and said microparticles are applied to said surface of said adhesive region as separate entities and wherein the microparticles create pockets between them which are occupied by the therapeutic agent and from which the therapeutic agent is released.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Harish teaches implantable device coated on preselected regions/portions of its outer surface with therapeutic agent (abstract; claims 3 and 18). The therapeutic agents are deposited on the surface of the device in the form of dry particles (page 3, 2nd and 3rd full paragraphs; claims 7 and 8). The device is covered by polymeric primer prior to applying the therapeutic particles to adhere the particle to the surface of the stent, i.e. adhesive (page 4, 1st full paragraph; page 13, 3rd full paragraph; page 16, 1st full paragraph). Therapeutic agents can be protein, which is a macromolecule, or biostable polymers (page 3, 4th full paragraph; page 8, 1st full paragraph; page 10, last paragraph; page 11, 1st full paragraph). The particles are spherical having diameter from about 5 to 20 microns (page 8, 3rd and 4th full paragraphs). The layer containing the particles is covered by polymeric topcoat that helps immobilization of the particles on the surface of the device and controls the release of the therapeutic agents from the surface of the device (page 17, 1st paragraph). The particles deposited on the surface of the device may be made of different substances (page 12, last paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Harish teaches therapeutic particles coated as dry powder on a stent by virtue of adhesive, and further teaches the particles may be made of different substances including biostable substances, however, the reference does not explicitly teach the therapeutic agent and the microparticles are separate entities as instantly claimed by amended claim 1.

Pilliar teaches implantable device partially coated with plurality of small discrete metallic particles bonded together at points of contact with each other to define a plurality of pores in the coating and adhere to the device (abstract; col.2, lines 40-56; col.5, lines 5-7). The coating provides the device with uniform strength (col.3, lines 30-33; col.4, lines 8-11; col.8, lines 38-42). The pores of the implant may be treated with therapeutic agent such as materials that promote the tissue growth or antibiotics before implantation (col.8, lines 28-32).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an implantable device coated with dry powdered particles of therapeutic agents and other biostable substances adhered to the surface of the device by primer as taught by Harish, and replace the particle of the other biostable substances with the metallic particles taught by Pilliar that adhere together to form pores. One would have been motivated to do so because Pilliar teaches that partial coating of implantable device with metallic particles provides the implantable device with uniform strength. Further, one would have been motivated to apply therapeutic agent along with metallic particles because Pilliar teaches that pores formed by the metallic particles can be treated with therapeutic agents before implantation. One would reasonably expect formulating an implantable device coated with dry powdered particles of therapeutic agents and metallic particles that are adhered together forming pores and

adhered to the surface of the device wherein the device has sufficient strength and controllably releases the particles of the therapeutic agents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46, 47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611